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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,715	08/09/2005	Kristin Wannerberger	052209-0132	5203

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EXAMINER	
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ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,715	WANNERBERGER ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,13 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *30 Dec 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Remarks

The Examiner thanks Applicants for the timely reply filed 6 February 2008, in the matter of 10/519,715.

Applicants' election **without traverse** of Group I, claims 1-8 and 13, in the reply filed on 6 February 2008 is acknowledged.

The Examiner further acknowledges that claim 14, which is clearly dependent from claim 13, should also be included with Group I, directed to a blister pack composition, rather than Group II, which is directed to a dosage form, as pointed out by Applicants.

The remaining claims 9-12 of Group II, are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The remaining claims 1-8, 13 and 14 are presented and represent all claims under consideration.

Information Disclosure Statement

An Information Disclosure Statement (IDS), filed 30 December 2004 is acknowledged and has been reviewed.

Specification

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "in association with" as recited in claim 1 renders the claim indefinite since it is unclear what form of relationship is conveyed between the active desmopressin and the pharmaceutically acceptable additives. Herein, and for the purposes of examination on the merits, the above phrase is broadly and reasonably interpreted by the Examiner as reciting the presence of desmopressin and a pharmaceutically acceptable additive in the same composition.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language.

The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 4 recites the broad recitation "...wherein said pH is in the range of from 4.0 to 5.0...", and the claim also recites "...preferably from 4.5 to 4.8" which is the narrower statement of the range/limitation.

Claim 5 recites the limitation "said agent" in lines 1 and 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 5 recites the broad recitation "...wherein said agent is

an acid…", and the claim also recites "…preferably an acid selected from the group consisting of citric acid, hydrochloric acid and malic acid" which is the narrower statement of the range/limitation. Herein, and for the purposes of examination on the merits, the Examiner broadly and reasonably interprets claim 5 as reciting an acid as the agent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Applicants' own admission on the record.

The instant claims are directed to a blister pack comprising blisters containing a solid dosage form of desmopressin and a pharmaceutically adjuvant, diluent or carrier (claim 1). The limitation of the claim wherein the solid dosage form "is adapted to prevent moisture related degradation of said desmopressin" is deemed a product-by-process limitation, which per MPEP §2113, holds no patentable weight. Claim 6 recites materials from which the blister packaging may be constructed (e.g. PVC, PVC/PVDC blends, and aluminum foil). Claim 8 recites solid dosage form limitations such as tablets, powders and wafer sheets.

Applicants' instant specification makes the following admission on the record:

"A Minirin® tablet has previously been marketed contained in a blister pack comprising polyvinyl chloride (PVC) blisters coated with PVDC (polyvinylidene chloride). An aluminium foil lid provided with a heat seal lacquer was utilised. The blister pack product was withdrawn from the market in 2002 due to a consistent problem with degradation of the desmopressin acetate during long term storage". Minirin® tablets, which are also defined as the generic compound desmopressin tablets or tablets comprising a DDAVP and a pharmaceutically acceptable carrier (see Example 8 of USPN 5,985,835 and Abstract of WO 85/02119).

Claims 1-5, 7, 8 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Flockhart et al. (USPN 5,298,256).

The instant claims are directed to a blister pack comprising blisters containing a solid dosage form of desmopressin and a pharmaceutically adjuvant, diluent or carrier, as discussed above. Claim 2 further limits the solid dosage of claim 1 such that it contains an agent which provides said dosage with a particular pH range on exposure to water. Claims 3 and 4 further limit the pH range of claim 2. The agent component recited in claims 2-4 is taught as a pH control agent. However, with regards to the properties of said agent, MPEP §2112.01(II) states that "[a] chemical compound and its properties are inseparable". Therefore any teaching of the claimed agent will also teach the pH range of values which it contributes to the overall composition. Claim 5 recites that the agent is an acid (e.g. citric, malic or hydrochloric). Claim 7 recites that the dosage *does not* comprise an enteric coating [emphasis added]. The instant independent claim 13 recites the same as claim 1

with the addition of the solid dosage limitations which include the pH controlling agent and which exclude (e.g. the dosage does not comprise) fish gelatin or an enteric coating.

Flockhart et al. teaches a pharmaceutical composition containing desmopressin as an active ingredient, said composition specifically being taught in the form a wafer sheet (e.g. buccal patch), wherein the desmopressin is contained in an erodible matrix (claims 1, 12 and 13). Said buccal patches are expressly taught as being packaged in blister packs (col. 5, lines, 25-30). Said erodible matrix is taught as further comprising an acid agent (e.g. myristic acid) (col. 5, line 60 to col. 6, line 5) and is silent as to the inclusion of any form of enteric coating contained with said dosage.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable Flockhart et al. (USPN 5,298,256) in view of Nilsson et al. (WO 03/094886).

The instant claims 1 and 13 are directed to a blister pack comprising blisters containing a solid dosage form of desmopressin and a pharmaceutically adjuvant, diluent or carrier, as discussed above. Claims 6 and 14 further limit the materials from which the blister packs are constructed.

The teachings to Flockhart et al. are discussed above. However, Flockhart does not expressly teach the materials used to prepare the blister packs.

Nilsson et al. teach solid, intrabuccally-disintegrating, pharmaceutical dosage formulations of desmopressin which have a sufficient strength for handling in and removal from blister packaging without disintegration (Abstract and pg. 3, lines 19-27). Nilsson further teaches by example, formulations which do not include an enteric coating or fish gelatin. For example, the formulation of Comparative Example 1 admixes solid desmopressin with liquid hydrochloric acid (HCl) and is used to form an injectable formulation. Comparative Example 2 teaches the formulation of a solid desmopressin tablet. Nilsson also expressly teaches the materials used in the preparation of said blister packaging because blister packaging constructions, which are further taught by Masaki et al. (USPN 5,466,464), and are thereby incorporated in full by reference. Masaki et al. teach the use of blister packaging which comprises polypropylene, polyvinyl chloride, polyvinylidene chloride and the like (col. 7, lines 53-64 and Example 8).

In view of the combined teachings of the prior art, one of ordinary skill in the pharmaceutical or biomedical art, at the time of the invention, would have been motivated to prepare a pH-controlled, solid desmopressin dosage form without an enteric coating in combination with blister packaging materials in order to achieve the instantly claimed packaged dose. Such would have been obvious in the absence of evidence to the contrary since Flockhart et al., expressly teaches the blister packaging of an uncoated, solid form of desmopressin encapsulated in an erodible buccal sheet matrix. Such would have been further obvious, since the teachings to both the Flockhart and Nilsson/Masaki references overlap in their dosages and packaging teachings.

A person of ordinary skill in the art would have a reasonable expectation of success in modifying the blister packaging material for the dosage form practiced by Flockhart et al. in view of the packaging materials taught by Nilsson/Masaki since the combined teachings disclose the instantly claimed dietary supplement.

All claims have been rejected; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615